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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/601,005	03/01/1996	KJELL BACKSTROM	06275/034001	2853
26161	7590	11/03/2004		
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110				
EXAMINER CHOI, FRANK I				
ART UNIT		PAPER NUMBER		
1616				

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/601,005

Applicant(s)

BACKSTROM ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 46,54-77 and 80-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46,54-58,61-77,80,82,83 and 96-101 is/are rejected.
- 7) ☒ Claim(s) 59,60,81,84-95 and 102-107 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/24/2002.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Priority*

Please amend first sentence of Specification after title to indicate the following:

"This application is a 371 of PCT/SE95/01542 filed on December 12, 1995."

### *Claim Objections*

Claim 74,75 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 74,75 do not indicate that the end result is that the medicament and the surfactant are suspended in the propellant as a finely divided powder, as such, it appears that the end product of the process is greater in scope than the claimed aerosol formulation in claim 46.

Claims 59,60,81,84-95,102-107 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims or if a terminal disclaimer is filed with respect to US Pat. 6,524,557.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46, 54-58, 61-77, 80, 82-83, 96-101 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10-41, 48-62, 74-105, 114-127 of U.S. Patent No. 6,524,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the US Patent are directed to pharmaceutical aerosol formulations, methods of using and methods of preparing the same containing HFA propellant, a polypeptide medication which is inhaled having a micron size of less than 10 microns and an alkyl saccharide surfactant where the medication is dispersed in the propellant and the surfactant is dispersed in the propellant as solid particles. The claimed invention is directed to a pharmaceutical aerosol formulation, methods of using and methods of preparing the same containing HFA propellant, a "medicament for inhalation" and an alkyl saccharide surfactant, where the medicament and surfactant are dispersed in the propellant as a finely divided powder. Since the polypeptide is a medicament and is inhaled one of ordinary skill in the art would recognize that the polypeptide is a "medicament for inhalation." Therefore, the claimed invention, as a whole, would have been an obvious modification of said claims of US Pat. 6,524,557 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the said claims of said US. Patent.

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*Conclusion*

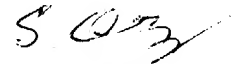
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

October 30, 2004



SABIHA QAZI, PH.D.  
PRIMARY EXAMINER